# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
KENTON R. MULLINS
STOUT, UXA, BUYAN & MULLINS, LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

# PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

| | |
|---|---|
| Date of mailing *(day·month·year)* | 19 AUG 2009 |
| Applicant's or agent's file reference MB8134PCT | **FOR FURTHER ACTION** See paragraphs 1 and 4 below |
| International application No. PCT/US 09/49728 | International filing date *(day·month·year)* 06 July 2009 (06.07.2009) |
| Applicant MAST BIOSURGERY AG | |

Article 19 Amendments due 10/19/09
IDS on us case due 11/19/09
CH II Demand/Resp. to Written Opinion Due 5/6/10

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   **Filing of amendments and statement under Article 19:**
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   **When?** The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   **Where?** Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 8270

   **For more detailed instructions**, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

| | |
|---|---|
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201 | Authorized officer:<br>Lee W. Young<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

ENTERED
DATE 8/24/09
BY

PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference MB8134PCT | FOR FURTHER ACTION | see Form PCT/ISA/220 as well as, where applicable, item 5 below. |
|---|---|---|
| International application No. PCT/US 09/49728 | International filing date *(day/month/year)* 06 July 2009 (06.07.2009) | (Earliest) Priority Date *(day/month/year)* 06 July 2008 (06.07.2008) |
| Applicant MAST BIOSURGERY AG | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the drawings to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 09/49728

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 13/00; A61K 9/70 (2009.01)
USPC - 424/443-444
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC - 424/443-444

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 424/93.7, 422, 426; 128/898; 521/50 (see search terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB; USPT; EPAB; JPAB); Google; Google Scholar
Search Terms Used: resorbable thin mebrane, absorbable, bio-absorbable, pericardial substitute, open heart surgery, pericardium, epicardium, lactide, poly-lactide, polymer, co-polymer, micron, stitches, heat bonding, uniform, smooth, non-porous, planar, adhesions

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | US 2008/0063686 A1 (CALHOUN et al.) 13 March 2008 (13.03.2008) para [0008]-[0009], [0011], [0028], [0042]-[0046], [0049]-[0050], [0056], [0058]; fig 1a, 2f; claim 1, 5, 21, 23, 33 | 1-15 |
| Y | US 2005/0074495 A1 (SCHWARTZ et al.) 07 April 2005 (07.04.2005) para [0039], [0108], [0132], [0209]-[0210] | 1-15 |
| Y | US 2004/0018175 A1 (DIMITRIJEVICH) 29 January 2004 (29.01.2004) para [0019], [0028], [0066], [0079], [0093], [0096] | 1-15 |

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 10 August 2009 (10.08.2009) | 19 AUG 2009 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201 | Authorized officer:<br>Lee W. Young<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

Form PCT/ISA/210 (second sheet) (April 2007)

# PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
KENTON R. MULLINS
STOUT, UXA, BUYAN & MULLINS, LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

# PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

| Date of mailing *(day/month/year)* | 19 AUG 2009 |
|---|---|

| Applicant's or agent's file reference | FOR FURTHER ACTION |
|---|---|
| MB8134PCT | See paragraph 2 below |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/US 09/49728 | 06 July 2009 (06.07.2009) | 06 July 2008 (06.07.2008) |

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 13/00; A61K 9/70 (2009.01)
USPC - 424/443-444

Applicant MAST BIOSURGERY AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| Name and mailing address of the ISA/US | Date of completion of this opinion | Authorized officer: |
|---|---|---|
| Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201 | 10 August 2009 (10.08.2009) | Lee W. Young<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 09/49728

**Box No. I Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 09/49728

**Box No. V** **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 1-15 | YES |
| | Claims | none | NO |
| Inventive step (IS) | Claims | none | YES |
| | Claims | 1-15 | NO |
| Industrial applicability (IA) | Claims | 1-15 | YES |
| | Claims | none | NO |

2. Citations and explanations:

Claims 1-15 lack an inventive step under PCT Article 33(3) as being obvious over US 2008/0063686 A1 to CALHOUN et al. (hereinafter 'Calhoun') in view of US 2005/0074495 A1 to SCHWARTZ et al. (hereinafter 'Schwartz') and further in view of US 2004/0018175 A1 to DIMITRIJEVICH.

Regarding claim 1, Calhoun teaches a method comprising adhesively (para [0045]) applying a resorbable thin membrane (para [0008]) over a treatment site of tissue after a treatment is conducted onto the tissue (para [0045], [0050]; claim 1). Calhoun does not teach applying a resorbable thin membrane over a treatment site of tissue before a treatment is conducted onto the tissue whereby the treatment is performed through the resorbable thin membrane. Schwartz teaches a method comprising adhesively (para [0132]) applying a resorbable membrane over a treatment site of tissue (para [0108] - The resorbable membrane is the bioresorbable association complex in membrane form) before a treatment is conducted onto the tissue (para [0039], [0108], [0209]-[0210] - The resorbable membrane is used to lubricate the tissue and surgical instruments prior to use, and the resorbable membrane reduces the formation of tissue adhesions during surgery). Dimitrijevich teaches a method comprising adhesively applying a resorbable membrane over a treatment site of tissue after a first treatment is conducted onto the tissue (para [0019], [0028], [0093], [0096] - The "resorbable membrane" is the anti-adhesion patch comprising an absorbable barrier, and the first treatment is the incision), whereby a second treatment is performed through the resorbable membrane (para [0066] - The second treatment is cutting through the anti-adhesion patch before the anti-adhesion patch is absorbed to work on cardiac vessels). It would have been obvious to one skilled in the art to combine the method taught by Calhoun plus applying a resorbable membrane over a treatment site of tissue before a treatment is conducted onto the tissue taught by Schwartz with the treatment performed through a resorbable membrane taught by Dimitrijevich in order to develop an improved method for: reducing trauma caused by an incision made through tissue, wherein trauma to tissue promotes the formation of tissue adhesions; and preventing the formation of tissue adhesions both during surgery and after surgery.

Regarding claim 2, Calhoun, Schwartz, and Dimitrijevich teach the method of claim 1. Calhoun and Schwartz do not teach wherein the treatment comprises an incision made through a layer comprising both the resorbable membrane and a membrane of the tissue. Dimitrijevich teaches wherein a treatment comprises an incision made through a layer comprising both a resorbable membrane and a membrane of the tissue (para [0019], [0066] - The "tissue" is the pericardium or epicardium). It would have been obvious to one skilled in the art to combine the method taught by Calhoun a smodified by Schwartz and Dimitrijevich, with the incision taught by Dimitrijevich in order to develop an improved method for reducing trauma caused by an incision made through a membrane of tissue and, thus, preventing the formation of tissue adhesions during surgery.

Regarding claim 3, Calhoun, Schwartz, and Dimitrijevich teach the method of claim 2. Calhoun teaches wherein the resorbable thin membrane is a substantially planar (fig 1a) anti-adhesion healing membrane (para [0008], [0050]; claim 1), which is:
(a) substantially-smooth on at least one side (para [0011]);
(b) substantially uniform in composition (para [0009]);
(c) about 10 microns to about 300 microns in thickness (claim 1);
(d) non-porous (para [0011]);
(e) constructed from a material comprising a resorbable polymer base material selected from one or more of (a) a poly-lactide polymer, (b) a copolymer of lactides, and (c) a poly-lactide polymer and a copolymer of lactides (para [0028]; claim 21); and
(f) adapted to be resorbed within a period of less than approximately 24 months from an initial implantation of the resorbable thin membrane (para [0049]; claim 33).

Regarding claim 4, Calhoun, Schwartz, and Dimitrijevich teach the method of claim 2. Calhoun and Schwartz do not teach further comprising placing a resorbable membrane over the resorbable thin membrane and over the incision. Dimitrijevich teaches placing a second resorbable membrane over a first resorbable membrane and over an incision (para [0019], [0028], [0096] - The second "resorbable membrane" is the second anti-adhesion patch comprising an absorbable barrier, and the first "resorbable membrane" is the anti-adhesion patch comprising an absorbable barrier). It would have been obvious to one skilled in the art to combine the method taught by Calhoun, as modified by Schwartz and Dimitrijevich, with the second resorbable membrane taught by Dimitrijevich in order to develop an improved method for preventing the formation of tissue adhesions after surgery, wherein resorbable membranes are resorbed at a safe, controlled, and effective rate.

----------continued in Supplemental Box----------

**Supplemental Box**

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box No. V 2. Citations and explanations

Regarding claim 5, Calhoun, Schwartz, and Dimitrijevich teach the method of claim 1. Calhoun and Schwartz do not teach further comprising placing a thin anti-adhesion resorbable membrane over the resorbable thin membrane and over the treatment site following the treatment. Dimitrijevich teaches placing a second anti-adhesion resorbable membrane over a first resorbable membrane and over a treatment site following a treatment (para [0019], [0028], [0096] - The second "anti-adhesion resorbable membrane" is the second anti-adhesion patch comprising an absorbable barrier and the first resorbable membrane is the anti-adhesion patch comprising an absorbable barrier). It would have been obvious to one skilled in the art to combine the method taught by Calhoun as modified by Schwartz and Dimitrijevich, with placing the anti-adhesion resorbable membrane over the resorbable membrane taught by Dimitrijevich in order to develop an improved method for preventing the formation of tissue adhesions during and after surgery, wherein thin resorbable membranes are resorbed at a safe, controlled, and effective rate.

Regarding claim 6, Calhoun, Schwartz, and Dimitrijevich teach the method of claim 1. Calhoun teaches wherein a thickness of the resorbable thin membrane is between about 100 and 200 microns (claim 5, 23).

Regarding claim 7, Calhoun, Schwartz, and Dimitrijevich teach the method of claim 1. Calhoun teaches wherein the resorbable thin membrane is a healing membrane provided in a sterile packaging (para [0058]).

Regarding claim 8, Calhoun, Schwartz, and Dimitrijevich teach the method of claim 7. Calhoun teaches wherein the step of placing the resorbable thin membrane in a patient is effective to attenuate tissue adhesion (para [0008]).

Regarding claim 9, Calhoun, Schwartz, and Dimitrijevich teach the method of claim 1. Calhoun teaches further comprising a step of attaching the resorbable thin membrane using stitches, wherein the attaching step comprises suturing through apertures on opposing edges of the resorbable thin membrane (para [0044]-[0045], [0056]; fig 2f). Calhoun and Schwartz do not teach an opening or gap of the resorbable membrane. Dimitrijevich teaches an opening or gap of a resorbable membrane (para [0066] - The "opening or gap" is the opening or gap that results from the surgeon cutting through the patch to gain access to the heart vessels under the patch). Calhoun, Schwartz, and Dimitrijevich do not teach lacing a suturing thread in a manner resembling an arrangement of a shoelace of a shoe, followed by pulling the suturing thread to close the opening or gap. It would have been obvious to one skilled in the art to combine the method taught by Calhoun, Schwartz, and Dimitrijevich with the opening or gap of the resorbable membrane taught by Dimitrijevich in order to develop an improved method for application in heart vessel repair wherein the trauma caused by an incision made through a membrane of tissue is reduced and, thus, the formation of tissue adhesions during surgery is reduced. It would have been obvious without undue experimentation to one skilled in the art to extend the step of attaching the resorbable membrane using stitches taught by Calhoun and extend the opening or gap taught by Dimitrijevich to include lacing a suturing thread in a manner resembling an arrangement of a shoelace of a shoe, followed by pulling the suturing thread to close the opening or gap in order to effectively secure the resorbable membrane to the tissue and, thus, prevent the formation of tissue adhesions during surgery and after surgery.

Regarding claim 10, Calhoun, Schwartz, and Dimitrijevich teach the method of claim 9. Calhoun and Schwartz do not expressly teach further comprising a step of attaching the resorbable thin membrane to a pericardial membrane using stitches. Calhoun teaches a step of attaching the resorbable membrane to muscular tissue using stitches (para [0045]-[0046] - The "stitches" are the sutures). Dimitrijevich teaches a step of attaching a resorbable membrane to a pericardial membrane using stitches (para [0019], [0028], [0079], [0096] - The "pericardial membrane" is the pericardium or epicardium, and the "stitches" are the sutures). It would have been obvious to one skilled in the art to combine the method taught by Calhoun, as modified by Schwartz and Dimitrijevich, including the step of attaching the resorbable membrane using stitches taught by Calhoun, with attaching the resorbable membrane to the pericardial membrane using stitches taught by Dimitrijevich in order to develop an improved method for preventing the formation of tissue adhesion during and after open heart surgery.

Regarding claim 11, Calhoun, Schwartz, and Dimitrijevich teach the method of claim 10. Calhoun teaches wherein the opposing edges have greater thicknesses than other regions of the resorbable thin membrane (para [0042]-[0043]; fig 2f).

Regarding claim 12, Calhoun, Schwartz, and Dimitrijevich teach the method of claim 11 but do not expressly teach wherein the attaching step comprises heat bonding the resorbable thin membrane to the pericardial membrane. Calhoun teaches heat bonding the resorbable thin membrane to muscular tissue (para [0045]-[0046]). Dimitrijevich teaches attaching a resorbable mebrane to the pericardial membrane (para [0019], [0028], [0079], [0096]). It would have been obvious without undue experimentation to one skilled in the art to extend the heat bonding attaching step taught by Calhoun and extend attaching a resorbable membrane to the pericardial mebrane taught by Dimitrijevich to include heating bonding the resorbable thin membrane to the pericardial membrane in order to develop an improved method, for application in open heart surgery, that reduces the formation of tissue adhesions during and after surgery.

----------continued in next Supplemental Box----------

**Supplemental Box**

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Prior Supplemental Box:

Regarding claim 13, Calhoun, Schwartz, and Dimitrijevich teach the method of claim 1. Calhoun teaches wherein the method further comprises a step of attaching the resorbable thin membrane using stitches, the attaching step comprising suturing through opposing edges of the layer comprising both a resorbable membrane and tissue (para [0044]-[0045], [0056]; fig 2f). Calhoun and Schwartz do not teach: wherein the treatment comprises an incision made through a layer comprising both the resorbable membrane and into the tissue; and the opening or gap of the layer. Dimitrijevich teaches a treatment comprising an incision made through a layer comprising both a resorbable membrane and tissue (para [0019], [0066] - The "tissue" is the pericardium or epicardium) and teaches an opening or gap of the layer (para [0066] - The "opening or gap" is the opening or gap that results from the surgeon cutting through the patch to gain access to the heart vessels under the patch). Calhoun, Schwartz, and Dimitrijevich do not teach lacing a suturing thread through opposing edges of an opening or gap of the layer in a manner resembling an arrangement of a shoelace of a shoe, followed by pulling the suturing thread to close the opening or gap. It would have been obvious to one skilled in the art to combine the method taught by Calhoun, as modified by Schwartz and Dimitrijevich, with the incision and opening or gap taught by the Dimitrijevich, in order to develop an improved method, for application in open heart surgery, wherein the trauma caused by an incision made through a membrane of tissue is reduced and, thus, the formation of tissue adhesions during surgery is reduced. It would have been obvious without undue experimentation to one skilled in the art to extend the attaching step taught by Calhoun and the opening or gap taught by Dimitrijevich to include lacing a suturing thread in a manner resembling an arrangement of a shoelace o a shoe, followed by pulling the suturing thread to close the opening or gap in order to effectively secure the resorbable membrane to the tissue and, thus, prevent the formation of tissue adhesions during surgery and after surgery.

Regarding claim 14, Calhoun, Schwartz, and Dimitrijevich teach the method of claim 13. Calhoun teaches wherein the opposing edges have greater thicknesses than other regions of the resorbable thin membrane (para [0042]-[0043]; Fig 2f).

Regarding claim 15, Calhoun, Schwartz, and Dimitrijevich teach the method of claim 13 but do not expressly teach wherein the attaching step comprises heat bonding the resorbable thin membrane to a pericardial membrane. Calhoun teaches heat bonding the resorbable thin membrane to muscular tissue (para [0045]-[0046]). Dimitrijevich teaches attaching a resorbable mebrane to a pericardial membrane (para [0019], [0028], [0079], [0096] - The "pericardial membrane" is the pericardium or epicardium). It would have been obvious without undue experimentation to one skilled in the art to extend the heat bonding attaching step taught by Calhoun and extend attaching a resorbable membrane to a pericardial mebrane taught by Dimitrijevich to include heating bonding the resorbable thin membrane to a pericardial membrane in order to develop an improved method, for application in heart vessel repair, that reduces the formation of tissue adhesions during and after surgery.

Claims 1-15 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

## INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

**What parts of the international application may be amended ?**

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

**When ?** Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

**Where not to file the amendments ?**

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

**How ?** Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

**The amendments must be made in the language in which the international application is to be published.**

**What documents must/may accompany the amendments ?**

**Letter (Section 205(b)):**

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

**The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.**

# SEQUENCE LISTINGS AND TABLES RELATED THERETO IN INTERNATIONAL APPLICATIONS FILED IN THE U.S. RECEIVING OFFICE

The Administrative Instructions (AIs) under the Patent Cooperation Treaty (PCT), in force as of **July 1, 2009**, contain important changes relating to the manner of filing, and applicable fees for, sequence listings and/or tables related thereto (sequence-related tables) in international applications. The complete text may be accessed at http://www.wipo.int/pct/en/texts/index.htm.

**Effective July 1, 2009**, Part 8 and Annex C-*bis* will no longer form part of the AIs. Part 8 was introduced in 2001 as a temporary solution to problems arising from the filing of very large sequence listings on paper and provided for a *sequence listing forming part of the international application* to be filed in electronic form on physical medium (*e.g.*, CD), together with the remainder of the application on paper. In 2002, Part 8 was expanded to include sequence-related tables and Annex C-*bis* was added to provide technical requirements. All applicants may now file complete international applications in electronic form, eliminating the need for these temporary provisions.

## I. AIS PART 8 AND ANNEX C-*BIS* DELETED AS OF JULY 1, 2009

A) **Sequence-related tables cannot be filed as a separate part of the description or in text format.** They must be provided as an integral part of the international application either:
- in PDF format as part of an international application filed in electronic form via EFS-Web; or
- on paper as part of an international application filed on paper.

B) A ***sequence listing forming part of an international application*** may be provided either:
- in electronic form, as part of an international application filed in electronic form via EFS-Web, in
  - Annex C/ST.25 text format (preferred), or
  - PDF format; or
- on paper as part of an international application filed on paper.

C) A ***sequence listing not forming part of the international application*** **(for search under PCT Rule 13*ter*) in Annex C/ST.25 text format**
- is not required where the *sequence listing forming part of the international application* was filed in Annex C/ST.25 text format as part of an international application filed in electronic form via EFS-Web
- is required for search where the *sequence listing forming part of the international application* was filed in PDF
- is required for search on physical medium (*e.g.*, CD) where the *sequence listing forming part of the international application* was filed on paper as part of an international application filed on paper.

## II. CALCULATION OF THE INTERNATIONAL FILING FEE AND FEE REDUCTION UNDER AI § 707

A) **A sequence-related table** must form an integral part of the international application and will incur FULL page fees with no upper limit.

B) A ***sequence listing forming part of an international application*** filed:
- via EFS-Web in Annex C/ST.25 text format will incur NO page fees;
- on paper or in PDF format will incur FULL page fees with no upper limit.

## III. AVAILABILITY OF SEQUENCE LISTINGS SUBMITTED FOR SEARCH UNDER PCT RULE *13TER*

International Searching Authorities will be required to transmit to the International Bureau a copy of an Annex C/ST.25 text format sequence listing provided for search under PCT Rule 13*ter*. Any such sequence listing will be made available on PATENTSCOPE® (*sequence listings forming part of the international application* are already available).

## IV. JULY 2009 REQUEST (PCT/RO/101)

The Request now has two options for the last sheet: one for paper filings; and one for EFS-Web filings. The July 2009 Request may be accessed at http://www.wipo.int/pct/en/forms/index.htm.